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| APPLICATION NO.     | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------|-------------|----------------------|---------------------|------------------|
| 10/740,208          | 12/18/2003  | Janez Kerc           | RG/G-33056A         | 2119             |
| 72554               | 7590        | 02/07/2008           | EXAMINER            |                  |
| SANDOZ INC          |             |                      | KENNEDY, SHARON E   |                  |
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|                     |             |                      | ART UNIT            | PAPER NUMBER     |
|                     |             |                      | 1615                |                  |
|                     |             |                      | MAIL DATE           | DELIVERY MODE    |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/740,208

Applicant(s)

KERC, JANEZ

Examiner

Sharon E. Kennedy

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 and 22-42 is/are pending in the application.
- 4a) Of the above claim(s) 7-18 and 22-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 19 and 30-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 7-18, 22-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 10, 2007.

Applicant states that claim 6 should be included in the examination. This is correct. This office action is being made non-final so that applicant may consider the art applied against claim 6.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 19, 30-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al. '693 in view of Glassman, US 3,186,910 or Scott '473. Regarding claim 6, newly examined in view of applicant's comments, see Clarke, column 10, line 47, disclosing the HPMC.

The claims now require a coating on the capsule body, and that the coating on the capsule and cap differ, by not being present on the cap or by being a different thickness. Clarke discloses all of the claimed components except for the coating. See the comments set forth in the previous office action. Clarke does disclose a dosage form having a plurality of subunits, each of which may comprise a different wall material (column 12, lines 43-52). For example, one capsule compartment may have a different wall material which releases the drug in a different part of the intestine or digestive tract. See column 13, lines 9-43. These wall compartments may be varied to have a release at a particular pH (column 13, line 39). Clarke also states that this may be accomplished by providing various wall thicknesses (column 13, lines 50-55), or have surface or other "construction features which modify their drug release characteristics". See column 14, lines 1-3. Again, in column 17, lines 54+, it is disclosed that the compartments may be made from different wall materials.

Applicant claims a capsule body and a capsule cap. The compartments of the Clarke patent include a closure cap 15 and body compartments. See figure 1. Clearly, Clarke discloses that various portions forming the dosage form may be made of different materials to achieve different release rates. Clarke does not disclose coatings to achieve the objective, but chooses different wall materials.

However, one of ordinary skill in the art would instantly recognize from reading the Clarke patent that forming different wall release rates can also be achieved by coating the parts of the Clarke dosage with materials to achieve this same function.

Glassman exemplifies that it is well known to coat capsule caps and bodies with different materials to facilitate, for example, dissolution in a given acid level to deliver different materials to different locations in the GI tract. Note especially column 2, lines 4-9, which discloses "novel means to spray coat one or both surfaces of the H-shaped capsule body portion or one or both caps with means to install in the gelatin itself resistance to dissolution in a given acid level." Accordingly, it is known to coat the various portions of a tablet with different coatings. Scott provides an updated reference on the coatings provided to ensure disintegration of the capsule at various locations within the GI tract. which show that these coatings are already known and discloses various thicknesses. It is agreed that Scott only discloses coating the cap and capsule with the same coating. However, coating only portions of capsules with coatings is known as shown by Glassman.

Accordingly, the examiner takes the position that it would be obvious to one of ordinary skill in the art to modify the Clarke chamber walls with coatings to control dissolution as shown by either of the secondary references. Clarke discloses that other ways may be used to modify the walls, and Clarke and Scott show the well-known methods of coatings.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Sharon E. Kennedy/*  
Sharon E. Kennedy  
Primary Examiner  
Art Unit 1615